In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 18-0267V

UNPUBLISHED

MARIA WERNING,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Filed: July 27, 2020

Chief Special Master Corcoran

Special Processing Unit (SPU); Entitlement; Ruling on the Record; Decision Without a Hearing; Causation-In-Fact; Pneumococcal Conjugate 13-Valent (Prevnar) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Jimmy A. Zgheib, Zgheib Sayad, P.C., White Plains, NY, for Petitioner.

Kimberly Shubert Davey, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On February 21, 2018, Maria Werning filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa–10, *et seq*.[2] (the "Vaccine Act" or "Program"), alleging that as a result of receiving a pneumococcal conjugate 13-Valent (Prevnar 13) vaccination on June 23, 2017, she suffered from a shoulder injury related to vaccine administration ("SIRVA"), including a complete tear of the biceps tendon, a large SLAP tear, partial-thickness tear of the anterolateral supraspinatus, impingement, spurring of the acromioclavicular joint, arthrosis of the acromioclavicular joint and inflammation. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed herein, I find that Petitioner is entitled to compensation.

[1] Because this unpublished ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). I intend to post this ruling on the United States Court of Federal Claims' website. **This means the ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

Ms. Werning filed her petition on February 21, 2018 (ECF No. 1). She filed the relevant medical records and a Statement of Completion the next day. (ECF No. 7-9). By November 2018, Respondent had reviewed all the documents in the case and filed a status report stating that he was amenable to settlement discussions. (ECF No. 24). Settlement discussions broke down in the late spring, however, and the parties requested a status conference. (ECF No. 36). A deadline was set for the filing of Respondent's Rule 4(c) to identify the areas of disagreement.

Respondent filed a Rule 4(c) report on August 26, 2019, in which he argues that "petitioner has not demonstrated that she is entitled to compensation based on a Table presumption of SIRVA" outlining each element of a SIRVA injury with which Respondent takes issue. (ECF No. 39). The parties agreed to brief the case (including any disputed factual issues) and requested a motion for ruling on the record. The parties have completed briefing, and this case is now ripe for adjudication. After a review of the entire record, I find that Petitioner is entitled to compensation.

II. Factual History

On June 23, 2017, Ms. Werning (age 65) received the Prevnar 13 vaccine in her right deltoid at the office of her primary care provider, Dr. Lacy Anderson, located at Integris Family Care in Norman, Oklahoma. Ex. 2 at 11-12, 84-85; Ex. 3 at ¶3; Ex. 4 at ¶3. There is no documented history of right shoulder injuries prior to this date.[3] *See* Exs. 2 and 3, *generally*. In her affidavit, Ms. Werning describes the circumstances of the vaccination, stating that she felt:

> significant pain in the area where the needle was placed. The severity of the pain was very unusual – unlike any other vaccine I had received in the past. It felt as if the needle was placed too high into my shoulder and caused to puncture something. Within minutes of receiving the vaccine, a lump developed at the injection site, and the nurse advised me to rub the area. That night, I had difficulty sleeping due to the pain. Over the next few days, the condition of my right shoulder worsened, and the pain began travelling down my entire arm.

Ex. 3 at ¶5. Ms. Werning explained that she had difficulty reaching behind her back and for high objects, lifting, doing household chores and other activities of daily living that required the use of her right shoulder. *Id*. at ¶6. She stated that she hoped that that the pain would go away on its own and she rested and modified her activities to avoid aggravating her condition. *Id*. at ¶7.

[3] Ms. Werning's medical history consisted of type 2 diabetes, hypertension, unspecified arthritis, right wrist pain, obesity, obstructive sleep apnea, unspecified osteoarthritis, and vitamin D deficiency. *See* Ex. 2 at 3, 6, 9; Ex. 3 at 1-85.

Approximately three and a half weeks later, on July 17, 2017, Ms. Werning called her physician's office to report that she was "having issues since vaccination" with her right shoulder and requested a return call from a nurse. Ex. 2 at 86. She stated that she never received a call back from her doctor's office. Ex. 3 at ¶8.

On August 28, 2017, Ms. Werning contacted her physician's office again and reported that she was "still having pain in her arm and is concerned due to this not resolving after two months." Ex. 2 at 87; Ex. 3 at 2, ¶9. She called to "get the name of the injection she was given so that she could research it." *Id*. Ms. Werning was offered a steroid pack but declined due to concerns about interactions with other medications she takes for diabetes. Ms. Werning requested an appointment with her physician as soon as possible. *Id*.

On September 8, 2017, Ms. Werning presented to her primary care physician ("PCP"), Dr. Lacy Anderson, complaining of right arm pain. Ex. 2 at 16. The notes from this visit state:

> P[atien]t here for severe R[ight] arm pain since getting her Prevnar 13 vaccine nearly 3 months ago. It hurts to touch her arm and was swollen for several weeks. She has a hard time with any movement of this arm. We offered her a steroid pack but she wanted to see me and have me take a peek at it.

Id. at 16. On examination, Ms. Werning was positive for myalgias of the right arm. *Id*. at 17. Dr. Anderson noted tenderness of the right arm with pain with both active and passive movement of the right arm at the shoulder. *Id*. at 18. In the assessment, Dr. Anderson noted: "[l]ooks like an injection reaction – p[atien]t reassured and we'll try a Medrol pack today." *Id*. at 16.

On September 11, 2018, Ms. Werning contacted her Anderson's office and requested a referral to an orthopedic for her right arm pain. Ex. 2 at 88. The referral was provided. *Id*.

On September 27, 2017, Ms. Werning presented to Dr. Vytautas Ringus at Orthopedic and Sports Medicine Center for an evaluation of her right shoulder. Ex. 5 at 27. Upon examination, Dr. Ringus noted that Ms. Werning exhibited right shoulder palpation at the incision site and some induration was also noted. He ordered and reviewed X-rays of her right shoulder which showed no abnormalities. *Id*. Dr. Ringus ordered an MRI for further evaluation. *Id.* at 28.

On October 4, 2017, Ms. Werning underwent an MRI of her right shoulder. Ex. 5 at 30. The MRI demonstrated a "1-1.5 cm high-grade undersurface partial-thickness tear of the anterolateral supraspinatus insertion with probably full thickness component… probably complete retracted tear of the biceps tendon…moderate probability large SLAP tear… inflammation, spurring and arthrosis of the acromioclavicular joint mild to moderately affecting the supraspinatus. Suggests impingement." *Id*.

On October 19, 2017, Ms. Werning presented to Dr. Ringus to discuss the results of her recent MRI. Ex. 5 at 25. Dr. Ringus noted that the MRI showed a likely "full-thickness supraspinatus tear without retraction bicipital rupture of the long head with retraction probably large SLAP tear likely signs of impingement acromioclavicular arthritis no other fractures or dislocations…" *Id*. Dr. Ringus described the MRI as "quite revealing." *Id*. He recommended that she attend physical therapy and return to the clinic in six weeks. *Id*.

On October 20, 2017, Ms. Werning returned to her PCP, Dr. Anderson, for a follow-up appointment. Ex. 2 at 94. Dr. Anderson noted that Ms. Werning "[s]aw Dr. Ringus for her right shoulder pain that started after her Prevnar injection. MRI shows tear and the injection just caused it to flare up. Will be doing P[hysical] T[herapy] for 6 weeks. Decided not to take the steroid pack due to uncontrolled glucose." *Id*. at 95.

Ms. Werning underwent a physical therapy evaluation of her right shoulder at Orthopedic and Sports Medicine Center on November 10, 2017. Ex. 5 at 21. Ms. Werning reported that she had no pain in her right shoulder until approximately three months earlier, "until receiving a pneumonia shot she believes that this shot was the onset of her pain." *Id*. She told the physical therapist that she wanted to avoid surgery if at all possible. *Id*. Ms. Werning rated her pain at this appointment as an 8 on a scale from 1 to 10. *Id*. The diagnosis was "likely R[ight] supraspinatus tear and SLAP lesion, resulting in decreased [range of motion] strength and overall functional ability, along with increased pain." *Id*. Her prognosis was listed as "fair" which "may vary or decline with decreased or inconsistent attendance to therapy and decreased patient compliance with HEP and other PT (physical therapy) recommendations." *Id*. at 24. Ms. Werning was prescribed physical therapy sessions two to three times weekly, up to 12 weeks as medically necessary. *Id*.

From November 10, 2017 through December 8, 2017, Ms. Werning attended 23 physical therapy sessions at Orthopedic & Sports Medicine Center. Ex. 3 at 2, ¶15; Ex. 5 at 21-22, 31. She recalled that her physical therapist told her that "the lump located at the injection site was the size of a baseball or fist and that he would have to massage it down." Ex. 3 at 2. Ms. Werning stated that eventually, she was released from physical therapy "due to the concerns of the increasing clicking and popping in my right shoulder. I was advised by my therapist that he did all that could be done and that I should explore other treatment options with my orthopedist." *Id*.

On December 28, 2017, Ms. Werning returned to Dr. Ringus for a follow-up visit of her right shoulder. Ex. 5 at 1. She reported that physical therapy had really helped her. Ms. Werning stated that her pain and swelling was much improved, although she still had occasional aches and pains, but the pain was tolerable. *Id*. She stated that she was happy with her progress. *Id*. Dr. Ringus noted that from his standpoint, Ms. Werning should finish her physical therapy and then complete her home exercise program. He instructed her to return to the clinic in 5-6 months. *Id.*

On January 24, 2018, Ms. Werning returned to Dr. Ringus for a follow up appointment for her right shoulder pain and to discuss possible surgical intervention. Ex.

5 at 35. She complained that her right shoulder pain had continued, and on examination her right arm demonstrated swelling. She also exhibited tenderness to palpation and continued to demonstrate some reduced range of motion. *Id*. The assessment included a complete tear of the right rotator cuff, arthritis of the acromioclavicular joint, subacromial impingement of the right shoulder, nontraumatic rupture of the right proximal biceps tendon, and a degenerative tear of the glenoid labrum of the right shoulder. *Id*. Dr. Ringus recommended surgery – a right shoulder arthroscopy, labeled debridement and possible rotator cuff repair, distal clavicle excision, and subacromial decompression. *Id* at. 35-36.

On March 13, 2018, Ms. Werning underwent surgical repair of her right shoulder. Ex. 7 at 1-3. The procedures included right shoulder arthroscopic extensive debridement, arthroscopic rotator cuff repair, arthroscopic subacromial decompression, and open distal clavicle excision. *Id*.

Two weeks later, she presented to Dr. Ringus for a post-operative follow-up appointment. Ex. 7 at 4. Ms. Werning stated that she had not yet begun post-operative physical therapy, but she felt her pain and strength were improving, and she was "pleased with progress." *Id*. On examination, Dr. Ringus noted that Ms. Werning's pain and swelling was resolving as expected. *Id*. Her surgery staples were removed, and she was instructed to follow up in four weeks. *Id*. at 5.

Ms. Werning underwent her first post-operative physical therapy session and evaluation on March 15, 2018. Ex. 13 at 73. Based on her physical examination, it was recommended that she attend physical therapy three times weekly, for up to 12 weeks. *Id*. at 75.

Ms. Werning attended physical therapy on multiple occasions in the spring of 2018 (March 16, 21, 26, 28, 29, and April 4, 6, 10, 19, 2018). At her April 20, 2019 re-evaluation appointment, Ms. Werning rated her pain as two to three out of 10. Ex. 13 at 49. She was still unable to perform functional reaching activities secondary to protocol restrictions. Ms. Werning stated she was independent with self-care activities including dressing and showering, and she was driving with minimal limitations. *Id*. Her surgery wounds were noted to be healing well and there were no signs of infection. *Id*. It was recommended that Ms. Werning continue with her physical therapy. *Id*. at 50.

On April 25, 2018, Ms. Werning returned to Dr. Ringus for her six-week post-operative appointment. Ex. 11 at 6. She reported that her pain and range of motion had improved, and she was regularly attending physical therapy. *Id*. Dr. Ringus reviewed X-rays taken earlier that day and noted "no worrisome findings." *Id*. Ms. Werning's right shoulder incisions were clean and well-healed. *Id*. Dr. Ringus allowed Ms. Werning to discontinue the use of her shoulder brace and encouraged her to continue with physical therapy. *Id*. at 7.

Ms. Werning attended 19 sessions of post-operative physical therapy from March 29, 2018 to June 12, 2018. Ex. 11. By June 13, 2018, Ms. Werning reported to Dr. Ringus that her right shoulder pain was "essentially resolved" and that she had done "great with

therapy and is here today for final follow-up." Ex. 8 at 6. Dr. Ringus noted that Ms. Werning's incisions were well-healed and that she had near full active and passive range of motion. *Id*. The O'Brien and Neer Hawkins shoulder impingement tests were negative. *Id*. Dr. Ringus agreed that Ms. Werning had done well with surgery and instructed her to continue with her home exercises. She was to return on an as-needed basis and had no restrictions on her activities. *Id*.

On July 1, 2019, more than one year later, Ms. Werning returned to Dr. Ringus complaining of continued right shoulder pain for the past two months. Ex. 13 at 77. She reported that her pain had been ongoing and slowly progressing. Ms. Werning rated her baseline pain at a five most days, but stated it was severe with certain movements. *Id*. Dr. Ringus ordered and reviewed x-rays during this appointment. He did not note any abnormalities. *Id*. However, Dr. Ringus ordered an MRI and prescribed pain medications to Ms. Werning, concerned that she may have reinjured her shoulder. *Id*. at 78. He instructed her to follow-up with him after her MRI. *Id*.

On July 17, 2019, Ms. Werning returned to Orthopedic and Sports Medicine Center as instructed after undergoing the MRI of her right shoulder the week prior. Ex. 12 at 6-8. The physician assistant noted that the MRI showed post-supraspinatus tendon repair, although there was no evidence of a recurrent tear. *Id*. The MRI did show "mild insertional tendinopathy or infraspinatus with a miniscule interstitial tear. Mild glenohumeral capsulitis with a small effusion. Mild chronic tendinopathy of distal subscapularis with a thin insertional interstitial laminar tear…" *Id.* Ms. Werning was encouraged to start attending physical therapy to improve her strength and to decrease the pain in her right shoulder. She was instructed to follow up in six weeks. *Id*.

On August 9, 2019, Ms. Werning returned to Orthopedic and Sports Medicine Center for an evaluation of her right shoulder. Ex. 13 at 29. She explained that her shoulder pain reoccurred three months prior and described her pain as a "burning sensation that travels down the arm just past the elbow." *Id*. It was noted that Ms. Werning had recently undergone surgery and had done well, but that now she was having trouble "lifting, reaching overhead, and using her dominant R[ight] arm. She often wakes up at night if she lays on her R[ight] side. She is a teacher and uses her arm a lot throughout the day…" *Id*. On examination, Ms. Werning had mild swelling on the lateral aspect of her right arm. She rated her pain as a two out of 10 and demonstrated decreased function of her right arm due to pain and a "globally" limited range of motion in her right shoulder. *Id*. She also displayed decreased strength. *Id*. Ms. Werning's prognosis was rated as "good for improvement of impairments & dysfunctions as well as pain reduction & return to function." *Id*. at 40. She was prescribed physical therapy three times weekly for up to 12 weeks. *Id*. at 41.

Ms. Werning attended physical therapy on August 13, 15, 16, 19, 21, 27, 28, 2019, and September 3, 5, 10, 2019. Ex. 13 at 15. In several of her sessions, she complained of increasing pain during her work hours, explaining that she was a teacher and worked long hours grading papers at a computer. *Id.* at 31.

Ms. Werning underwent a physical therapy re-evaluation at Orthopedic and Sports Medicine Center on September 18, 2019. Ex. 13 at 11. While Ms. Werning demonstrated an increase in the range of motion, strength, and function of her right shoulder, she was still experiencing pain with radicular symptoms. *Id*. at 12. It was recommended that Ms. Werning continue with physical therapy, three times weekly for up to another 12 weeks as medically necessary. *Id*.

At her September 25, 2019 physical therapy appointment, Ms. Werning reported that her right shoulder was "feeling better." Ex. 13 at 7. The range of motion of her shoulder was improved in all planes except internal rotation. *Id*. The plan was for Ms. Werning to return in three weeks, with decreasing sessions, up to 12 weeks as medically necessary. *Id*.

On October 3, 2019, Ms. Werning presented to Physical Therapist, Rachel Rose, for a follow up appointment. Ex. 13 at 5. Ms. Werning explained that she had not been in physical therapy recently due to a recent molar removal. *Id*. She had been on pain medication and reported that she had been feeling well and had increased shoulder mobility. *Id*. Ms. Rose noted that Ms. Werning performed her exercises well during her session, with minimal instruction. *Id*. The Plan of Care stated that Ms. Werning would continue to proceed as advised by her physician. *Id*. at 6.

By her October 18, 2019 physical therapy session, Ms. Werning reported that she was pleased with her progress. Ex. 13 at 47. She still had pain but felt that her pain was now manageable, and she intended to continue with her home exercise program. *Id*. Upon examination, Ms. Werning displayed improved range of motion and strength. *Id*. All her shoulder stability tests were negative, although she displayed some tenderness over the anterior shoulder, rotator cuff interval. *Id*. The physical therapist noted that a continued home exercise program and management were optimal. Ms. Werning was instructed to follow up as needed. *Id*. She declined any additional steroid injections due to her uncontrolled diabetes. *Id*.

Despite her improvement, Ms. Werning states that she continues to suffer from right shoulder pain, discomfort, swelling, weakness, and limited range of motion. Ex. 3 at 5, ¶19. She continues to have difficulty reaching, lifting, pulling and stretching, especially with overhead activities. Ex. 14 at 1. Ms. Werning states she is unable to sleep without discomfort and becomes easily irritated and depressed due to the fatigue. She continues to have difficulty performing household chores, grocery shopping, cooking, driving and other activities of daily living. Ms. Werning is right-hand dominant and states that her injury has made it "excruciatingly difficult to perform my daily activities without assistance." *Id*.

In describing her shoulder pain since her SIRVA injury, Ms. Werning stated that the limitations in the use of her right shoulder were especially apparent over the holiday season in 2017. Ex. 3 at 2, ¶17. She experienced severe pain when she was cooking, lifting pots and cutting vegetables. *Id*. She had significant difficulty with self grooming as she was unable to raise her right hand high enough to wash or blow dry her hair. *Id*. Ms.

Werning needed the assistance of her husband to get dressed, and she recalled significant limitations with driving. *Id*.

Ms. Werning also filed an affidavit from her husband, Stewart Wilcox-Sollof. Ex. 4. He confirmed that his wife had no issues with her right shoulder prior to vaccination. *Id*. He described the day after Ms. Werning received the Prevnar 13 vaccination, stating that he witnessed her crying in the kitchen after she got home from work. *Id*. This was concerning to him because he stated that his wife does not cry often. *Id*. He recalled that his wife complained about being in excruciating pain at the injection site since receiving the vaccination and that the pain was worsening. *Id*. He observed his wife in pain and discomfort as she slept. He stated that she continued to suffer from persistent pain, weakness, discomfort, clicking and popping in her right shoulder and that her sleep continues to be disturbed by the pain. *Id*. at 2.

III. Parties' Arguments

Ms. Werning requests that I issue a ruling finding that she is entitled to compensation in this case. Petitioner's Motion for Ruling on the Record ("Mot.") at 2. She avers that her SIRVA attributable to the Prevnar 13 vaccine is an injury listed on the Vaccine Injury Table, and thus she is entitled to a presumption of causation. Mot. at 1-2. Addressing each requirement for a Table SIRVA as set forth in the *Qualifications and Aids to Interpretation ("QAI")*, Ms. Werning maintains that her injury meets the definition of a Table SIRVA. *Id.* at 10-15; *see* 42 C.F.R. § 100.3(c)(10) (2017) (the additional QAI requirements for SIRVA). Petitioner further avers that she has suffered from her SIRVA for more than six months and has not filed a civil action or received an award or settlement for her SIRVA. Petition at 5; Section 11(c)(1)(D)(i) (statutory six-month requirement); Section 11(c)(1)(E) (requirement that Petitioner not have received an award or settlement of a civil action).

In the alternative, Ms. Werning alleges that she suffered a non-Table shoulder injury caused in fact by the Prevnar 13 vaccine she received. Memo at 2. She requested the opportunity to file a supportive expert report or present additional evidence should the Court deem it necessary that Petitioner proceed on her causation-in-fact claim. *Id.* at 15.

Respondent argues that Petitioner has failed to satisfy the criteria for a Table SIRVA because she has not provided preponderant evidence that she "experienced shoulder pain in the vaccinated shoulder within 48 hours of the allegedly causal vaccination." Respondent's Brief ("Opp.") at 5-6 (citing 42 C.F.R. § 100.3(a)(XIV)(B) (Table entry for SIRVA following the influenza vaccine) and (c)(10) (additional criteria for SIRVA set forth in the QAI)). Respondent maintains "the contemporaneous medical records are vague as to onset and do not establish by preponderant evidence that the onset of petitioner's right shoulder pain began within 48-hours of vaccine administration." Opp. at 6.

Respondent also argues that Petitioner's shoulder pain was not limited to her right shoulder, maintaining that the medical records establish that petitioner experienced pain

down her entire arm, all the way to her arm. Opp. at 7. And he maintains that because Ms. Werning had evidence of degenerative tears as demonstrate on an MRI that could explain her symptoms, she cannot satisfy the requirements for a SIRVA claim. *Id.* Respondent also states that because at Ms. Werning's first post-vaccination doctor's appointment, her range of motion of her shoulder was noted to be normal, this finding was not consistent with SIRVA. *Id*.

Finally, Respondent argues that Petitioner has not proven a causation-in-fact claim because she has not offered a reputable scientific or medical theory establishing that her Prevnar vaccine caused her alleged shoulder injury, nor has she presented evidence establishing that the time between her vaccination and the onset of symptoms would be considered "medically acceptable to infer causation-in-fact." Opp. at 8-9.

Ms. Werning filed a Reply addressing each of Respondent's arguments, and her responses are considered below.

IV. Fact Findings and Ruling on Entitlement

a. Legal Standards

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding her claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Human Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Human Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[4] a petitioner must

[4] In summary, a petitioner must establish that she received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of her injury for more than six months, died from her injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* § 11(c)(1)(A)(B)(D)(E).

establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of an influenza vaccine. 42 C.F.R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> *Shoulder injury related to vaccine administration (SIRVA).* SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10).

If, however, petitioner suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, she must prove that the administered vaccine caused injury to receive Program compensation. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. § 13(a)(1)(A). The Federal

Circuit has held that to establish an off-Table injury, petitioner must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that a petitioner "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface,* 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in a three-pronged test set forth in *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Under this test, a petitioner is required

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.* Circumstantial evidence may be considered, and close calls regarding causation must be resolved in favor of the petitioner. *Id.* at 1280.

A. Factual Findings Regarding QAI Criteria for Table SIRVA

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has satisfied the QAI requirements for a Table SIRVA.

1. Prior Condition

The first requirement under the QAIs for a Table SIRVA is a lack of a history revealing problems associated with the affected shoulder which were experienced prior to vaccination and would explain the symptoms experienced after vaccination. 42 C.F.R. § 100.3(c)(10)(i). Respondent has not contested that Petitioner meets this criterion, and I find that she has demonstrated a lack of history of pain, inflammation, or dysfunction of her right shoulder that would explain her symptoms. *See* Respondent's Rule 4(c) Report at 2; Ex. 2 at 1, 2-4, 37, 52-53, 85.

2. Onset of Pain

In order to meet the definition of a Table SIRVA, a petitioner must show that she experienced the first symptom or onset within 48 hours of vaccination (42 C.F.R. § 100.3(a)(XIV)(B)) and that her pain occurred within that same 48-hour period (42 C.F.R. § 100.3(c)(10)(ii) (QAI criteria)).

To support his position, Respondent cites the 24 days that lapsed before Ms. Werning complained of and sought medical care of her right shoulder pain. Opp. at 6. Because Ms. Werning did not seek medical treatment within 48 hours of vaccination, and because the contemporaneous records "are vague as to onset and do not establish by preponderant evidence that the onset of petitioner's right shoulder pain began within 48-hour so vaccine administration," Respondent argues that I should find that the onset requirement has not been met.

I find Respondent's arguments to be wholly unpersuasive. First, the records show that Ms. Werning *did* contact her doctor's office in a relatively timely manner (i.e. less than a month after vaccination). It is common for a SIRVA petitioner to delay seeking treatment, thinking her injury will resolve on its own, since patients are often told by medical providers at the time of vaccination to expect some soreness and pain for a period of time after. Ms. Werning confirms in her affidavit that she expected the pain to resolve on its own and waited before contacting her physician. Ex. 3 at 3. I find the length of time Ms. Werning waited before contacting her physician's office to report her shoulder pain to be entirely reasonable in these circumstances, and not suggestive of an onset longer than permitted by the Table.

Second, the medical records corroborate the contention that Petitioner's pain began within 48 hours of vaccination. There are a number of references in the records to Ms. Werning experiencing pain "since" or "after" receiving her flu shot. *See* e.g., Ex. 2 at 86 (Ms. Werning reports that she as "having issues since vaccination" with her right shoulder), 87 (Petitioner "is still having pain in her arm and is concerned due to this not resolving after two months"), 16 ("P[atien]t here for severe R[ight] arm pain since getting her Prevnar 13 vaccine nearly 3 months ago"), and 95 ("[s]aw Dr. Ringus for her right shoulder pain that started after her Prevnar injection"); Ex. 5 at 21 (Petitioner reported no pain in her right shoulder until approximately three months earlier, "until receiving a pneumonia shot she believes that this shot was the onset of her pain"). By contrast, there are no records, nor has Respondent identified a single record, that contain contradictory statements supporting the conclusion that onset was longer. I thus find unpersuasive Respondent's argument that Petitioner's self-reporting of shoulder pain is insufficient to establish onset within 48 hours, especially since she was seen by a physician so close in time to when she received the vaccination and consistently reported that the pain occurred immediately after vaccination.

As the Federal Circuit has noted, it is appropriate for a special master to give greater weight to evidence contained in medical records created closer in time to the vaccination, even if the information is provided as part of a medical history. *Cucuras*, 993

F.2d at 1528 (medical records are generally trustworthy evidence). The Circuit Court explained that

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Id. Based upon the above, I find there is preponderant evidence which establishes the onset of Ms. Werning's right shoulder pain was more likely than not immediate, and thus within 48-hours of vaccination.

3. Scope of Pain and Limited ROM

I likewise find that the scope of pain and limited range of motion was limited to Petitioner's right shoulder. To establish a Table SIRVA, a petitioner's pain and reduced ROM must be limited to the shoulder in which the vaccination alleged as causal was administered. 42 C.F.R. § 100.3(c)(10)(iii). Respondent argues that because Ms. Werning complained at her first post-vaccination appointment that she experienced "shooting/throbbing pains at times all the way down into her hand," and that in August 2019, she also described pain as traveling down her arm past the elbow, that she has not met this criterion. But this argument is not persuasive.

Ms. Werning complained of, was diagnosed with, and received treatment solely for a right shoulder injury. She developed a palpable lump at the injection site (her right shoulder) that lasted for months after vaccination. Ex. 3 at ¶5; Ex. 5 at 27. Her physicians documented that she had a reaction to her right shoulder from her vaccination. Ex. 2 at 16. An MRI of Ms. Werning's right shoulder confirmed a right shoulder injury, including a torn rotator cuff and SLAP tear. Most notably, during Ms. Werning's initial physical therapy evaluations and later sessions, her entire right shoulder and arm were thoroughly examined, and the assessment of her injury and her therapy was focused on her right shoulder. The assessment listed in her physical therapy records state: "(1) Complete tear of the right rotator cuff, (2) Pain in right shoulder, (3) Stiffness of right shoulder, not elsewhere classified, (4) Atrophy of muscle of right shoulder." Ex. 5 at 36. While I acknowledge Ms. Werning did initially mention pain travelling to her hand shortly after vaccination and once again after her shoulder surgery, I find that there is preponderant evidence in her medical and treatment records to find her pain and limited range of motion was limited to her right shoulder.

Ms. Werning was diagnosed and treated solely for pain and limited range of motion to her right shoulder. I therefore find that there is preponderant evidence to support a finding that Petitioner's pain and reduced range of motion was limited to her right shoulder. Thus, she satisfies the third criterion for a SIRVA injury.

4. Other Condition or Abnormality

The last QAI criteria for a Table SIRVA states that there must be no other condition or abnormality which would explain a petitioner's current symptoms. 42 C.F.R. § 100.3(c)(10)(iv). Respondent makes a very brief argument that Petitioner had evidence of degenerative tears that could explain her right shoulder symptoms. Opp. at 7. However, in the vast majority of SIRVA claims where petitioners undergo an MRI of the affected shoulder, there is evidence of degenerative symptoms of the shoulder, especially in certain specific age groups of the population. Ms. Werning was 67 years-old at the time she underwent the MRI of her right shoulder. It is not uncommon to find such evidence of degeneration of the shoulder on an MRI scan, and it does not rise to the level of a disqualifying fact for purposes of establishing a SIRVA claim.

I also note that Ms. Werning's primary care physician identified the Prevnar vaccine as the source of Petitioner's shoulder injury, noting that Ms. Werning "[s]aw Dr. Ringus for her right shoulder pain that started after her Prevnar injection. MRI shows tear and the injection just caused it to flare up." Ex. 2 at 94-95.

Thus, the record contains preponderant evidence establishing that there is no other condition or abnormality which would explain the symptoms of Petitioner's right shoulder injury.

A. Other Requirements for Entitlement

In addition to establishing a Table injury, a petitioner must also provide preponderant evidence of the additional requirements of Section 11(c). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence to fulfill these additional requirements.

The record shows that Petitioner received the Prevnar vaccine intramuscularly in her right arm on June 23, 2017, at the office of her primary care physician located in Norman, Oklahoma. Ex. 2 at 11-12, 84-85; Ex. 4 at ¶4; *see* Section 11(c)(1)(A) (requiring receipt of a covered vaccine); Section 11(c)(1)(B)(i)(I) (requiring administration within the United States or its territories). There is no evidence that Petitioner has collected a civil award for her injury. Petition at 5-6; Section 11(c)(1)(E) (lack of prior civil award).

As stated above, I have found that the onset of Petitioner's right shoulder pain was immediate and thus, within 48 hours of vaccination. *See* 42 C.F.R. § 100.3(c)(10)(ii) (setting forth this QAI requirement). This finding also satisfies the requirement that Petitioner's first symptom or manifestation of onset occur within the time frame listed on the Vaccine Injury Table. 42 C.F.R. § 100.3(a)(XIV)(B) (listing a time frame of 48 hours for a Table SIRVA following receipt of the influenza vaccine). Therefore, Petitioner has satisfied all requirements for a Table SIRVA.

The last criteria which must be satisfied by Petitioner involves the duration of her SIRVA. For compensation to be awarded, the Vaccine Act requires that a petitioner suffer

the residual effects of his or her left shoulder injury for more than six months. *See* Section 11(c)(1)(D)(i) (statutory six-month requirement). The records demonstrate, and Respondent does not contest, that Ms. Werning suffered the residual effects of her shoulder injury for more than six months. *See*, e.g., Ex. 7 at 1-3 (the records of Ms. Werning's right shoulder surgery). Thus, this requirement is also met.

Based upon all of the above, Petitioner has established that she suffered a Table SIRVA. Additionally, she has satisfied all other requirements for compensation. I therefore find that Petitioner is entitled to compensation in this case.

In view of the evidence of record, I find that Petitioner is entitled to compensation.

V. Conclusion

For all of the reasons discussed above and based on consideration of the record as a whole, **I find that Petitioner's right shoulder injury meets the definition for a Table SIRVA. Thus, causation is presumed, and Petitioner is entitled to compensation in this case. A separate damages order will be issued.**

IT IS SO ORDERED.

s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master